PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 21018643	**FOR FURTHER ACTION** See Form PCT/IPEA/416	
International application No. PCT/EP2005/001887	International filing date *(day/month/year)* 27.02.2005	Priority date *(day/month/year)* 24.02.2004
International Patent Classification (IPC) or national classification and IPC INV. A61B5/024 A61B5/0444		
Applicant NEOVENTA MEDICAL AB et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 4 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
21.12.2005	14.06.2006
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Kurze, V Telephone No. +49 89 2399-7380

Form PCT/IPEA/409 (Cover Sheet) (April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2005/001887

Box No. I Basis of the report

1. With regard to the **language**, this report is based on

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3(a) and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4(a))
   - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-20 as originally filed

Claims, Numbers

1-21 filed with telefax on 24.05.2006

Drawings, Sheets

1/11-11/11 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☒ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☒ the claims, Nos. 22,23
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-21
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-21
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-21
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

1. Subject-matter
The invention pertains to an apparatus and method for fetal heart monitoring.

2. Novelty
Document D1 (US-A-4 510 944) is considered the closest prior art. It discloses a similar apparatus as defined in claim 1. The device according to claim 1 differs from D1 in the feature d) of claim 1 and method step d) of claim 20. In particular, D1 does not teach dividing the fetal heart rate data into periods of time for polynomial curve fits for each period of time.
D1 does not disclose these features. The other documents cited in the Search Report are more remote. Therefore, claim 1 is novel.

3. Inventive step
The problem, the differentiating features solve is how to perform a statistical analysis and data reduction of fetal heart rate development over time.

The solution as defined in claims 1 and 20 by the differentiating features, has neither been disclosed, nor suggested in, nor rendered obvious by, any available document of the prior art. Therefore, claim 1 involves an inventive step.

CLAIMS

1. An apparatus for fetal monitoring comprising:
a) means for determining a fetal heart rate development over time,
b) means for identifying a primary fetal heart rate component which is required to shift a volume of blood from the heart to the cardiovascular system,
c) means for subtracting the primary component from the determined fetal heart rate to determine a residual component; and
d) means for using said residual component for analysis of the fetal heart rate beat-to-beat variation,

wherein the primary fetal heart rate component is identified through a polynomial curve fit approximation of the fetal heart rate data, and by:

(i) dividing the fetal heart rate data into periods of time of a predetermined size; and

(ii) performing individual polynomial approximations of the fetal heart rate data for each period of time.

2. An apparatus as claimed in claim 1, wherein said means for identifying the primary fetal heart rate component is adapted to perform the following steps:

(i) linear interpolation of recorded fetal heart rate data;

(ii) resampling at a resampling frequency, thereby forming a resampled series of fetal heart rate data, and;

(iii)polynomial curve fit approximation of said resampled series.

3. An apparatus as claimed in claim 1 or 2, wherein the polynomial curve fit approximation utilises polynomials of at least the 5th order.

4. An apparatus as claimed in claim 3, wherein said polynomials are of the 5th order.

5. An apparatus as claimed in claim 3, wherein said polynomials are of the 12th order.

6. An apparatus as claimed in any one of the preceding claims, wherein the polynomial approximation is obtained through a least squares approximation.

7. An apparatus as claimed in any one of the preceding claims, wherein each polynomial approximation is constrained such that neighbouring polynomial functions align and have equal first derivatives at the period border where they join.

8. An apparatus as claimed in any one of the preceding claims, wherein the predetermined size is greater than or equal to a time corresponding to 20 consecutive heart rate samples.

9. An apparatus as claimed in claim 7, wherein the predetermined size is a time corresponding to 20 consecutive heart rate samples.

10. An apparatus as claimed in any preceding claim, wherein the means for using said residual component for analysis of the fetal heart rate beat-to-beat variation is adapted to apply statistical tests for analysing the residual component in order to determinc the response of the fetus.

11. An apparatus as claimed in claim 10, wherein the statistical test comprises monitoring of a 95th percentile of the fetal heart rate residual component.

12. An apparatus as claimed in claim 11, wherein the statistical test further comprises calculating a median and a variance of said 95th percentile over a predetermined period of time.

13. An apparatus as claimed in claim 12, wherein said predetermined period of time is longer than 10 minutes.

14. An apparatus as claimed in any one of claims 11 to 13, wherein if the median of the 95th percentile is consistently below 3ms the fetal heart rate is classed as abnormal and non-reactive.

15. An apparatus as claimed in any one of claims 10 to 13, wherein said means for using said residual-component for analysis of the fetal heart rate beat-to-beat variation is adapted to indicate a significant reduction of fetal reactivity given a recording of the median of the 95th percentile below 2.3 ms and the variance of the 95th percentile below 0.1 over an extended period of time.

16. An apparatus as claimed in any one of claims 10 to 13, wherein said means for using said residual component for analysis of the fetal heart rate beat-to-beat variation is adapted to indicate a significant reduction of fetal reactivity given a recording of a decreasing trend of the median of the 95th percentile over an extended period of time.

17. An apparatus as claimed in any one of claims 10 to 13, wherein said means for using said residual component for analysis of the fetal heart rate beat-to-beat variation is adapted to exclude an abnormally low fetal heart rate variation if the median of the 95th percentile is consistently above 3ms.

18. An apparatus as claimed in claim 10, wherein the statistical test comprises monitoring of a short term, e.g. 3-4ms, frequency distribution of the fetal heart rate residual component.

19. An apparatus as claimed in claim 18, wherein if a 3-4ms frequency distribution is less than 7% the fetal heart rate is classed as non-reactive.

20. A method for fetal monitoring comprising the steps of:
a) determining a fetal heart development rate over time,
b) identifying a primary fetal heart rate component which is required to shift a volume of blood from the heart to the cardiovascular system,
c) subtracting the primary component from the determined fetal heart rate to determine a residual component; and
d) using said residual component for analysis of the fetal heart rate beat-to-beat variation.,

wherein the primary fetal heart rate component is identified through a polynomial curve fit approximation of the fetal heart rate data, and by:

(i) dividing the fetal heart rate data into periods of time of a predetermined size; and

(ii) performing individual polynomial approximations of the fetal heart rate data for each period of time.

21. A computer program for executing the steps of claim 20 when the programme is executed in a programmable apparatus according to claim 1.